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No. 92-303

Supreme Court, U.S.
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IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

ALBERT SLATER,
Petitioner,

v.

OPTICAL RADIATION CORPORATION,
Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Seventh Circuit

REPLY BRIEF FOR PETITIONER

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The principle flaw in respondent's opposition is its view that the marketing approval of a medical device by the Food and Drug Administration ("FDA"), standing alone, insulates the device's manufacturer from state-law liability. To be sure, that position comports with the decision of the court of appeals (5a). However, as we explained in our petition (Pet. 9-17), it finds no support in the preemption provision of the Medical Device Amendments ("MDA"), 21 U.S.C. § 360k(a), as authoritatively interpreted by the FDA, 21 C.F.R. § 808.1. Nor does it square with this Court's Supremacy Clause jurisprudence or with the approach taken by a majority of the lower courts in MDA preemption cases.

1. Despite respondent's protestations to the contrary (Opp. 11-15), the court of appeals' holding is fundamentally at odds with this Court's recent decision in *Cipillone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), for two related reasons. First, unlike the court of appeals here, *Cipillone* carefully analyzed the theory of the plaintiff's causes of action, asking not whether the claims had to do with "smoking and health" as a general matter, but whether, and to what degree, those claims threatened to impose the same type of substantive requirement that was already imposed by the relevant federal law, which required health warnings on cigarette packages and advertising. *Id.* at 2621-25. Thus, the plaintiff's duty-to-warn claims were preempted, but his breach of warranty and fraud claims were not (*see* Pet. 16). Similarly, here, the statute expressly preempts state-based device requirements, not simply because they concern "safety and effectiveness," *see* 21 U.S.C. § 360k(a), as the court of appeals held (5a), but when, and only when, the FDA has also issued specific requirements that involve the precise subject matter regulated by state law. *Id.*; *see also* 21 C.F.R. § 808.1(d). Because the FDA has not regulated any of the subjects that form the foundation for petitioner's complaint -- design defect, failure to warn, and breach of warranty -- there is no preemption under *Cipillone* (*see* Pet. 16-17).

Second, respondent maintains that the FDA's decision to allow it to market its intraocular lens ("IOL"), in effect, constituted approval of the device's "safety and effectiveness," and thus precludes petitioner's state-law claims under 21 U.S.C. § 360k(a). While respondent and the court of appeals purport to connect this argument with the statute's language -- "safety and effectiveness" -- they overlook the fact that there is no comparable substantive federal requirement, let alone one that conflicts with petitioner's state law remedies, which the statute and the regulations clearly demand. Thus, in reality, respondent is arguing that the approval

process for IOLs *impliedly* preempts *all* claims against a manufacturer once its device gains FDA approval. This argument fails not only because the FDA never passed on the safety or effectiveness of respondent's IOL, but, more importantly, because the doctrine of *implied* preemption is inapplicable where, as here, Congress has *expressly* defined the boundaries of state and federal power. *Cipollone*, 112 S. Ct. at 2618.

2. Like the court of appeals, respondent largely overlooks the FDA's regulatory framework for analyzing MDA preemption claims. As we have noted (Pet. 11-12), preemption may occur only when a state or local government regulates with respect to the same device and the same subject matter that is already the topic of federal regulation (what the FDA refers to as the need for "specific counterpart" regulations). *See generally* 21 C.F.R. § 808.1(d); 43 Fed. Reg. 18,661, 18662 (May 2, 1978). There is nothing in the MDA or the regulations promulgated thereunder to suggest that the mere existence of an approval mechanism for devices -- investigational or otherwise -- preempts any action against the manufacturer once the device is approved. Indeed, although completely ignored in respondent's brief, the FDA's regulations expressly state that state-law consumer protection and breach of warranty claims are *not* preempted because they apply generally to products and conduct beyond medical devices and their manufacturers. *See* 21 C.F.R. § 808.1(d)(1); *cf. Cipillone,* 112 S. Ct. at 2622, 2623-24 & n.27 (fraud, misrepresentation, and warranty claims are not preempted because they are based on general tort duty not to deceive or on the contractual relationship between parties, not on "smoking and health").

For much the same reason -- misinterpretation of the FDA's regulations -- respondent fails to come to grips with the divergence between the approach to MDA preemption

taken by the Seventh Circuit and that taken by most other courts.[1] Respondent's discussion of this authority does little more than note that those cases deal with devices other than IOLs *(i.e.,* tampons and hearing aids)(Opp. 15-18). But even before *Cipillone*, the Fifth Circuit (*Moore* and *Smith*), the New Jersey Supreme Court (*Long*), and most, but not all, of the federal district court cases (Pet. 13 n.2) carefully analyzed the MDA's narrow preemption principles and the precise substantive area regulated by the FDA, comparing the federal regulation with the state law remedy or regulation, and finding preemption only where there existed a direct conflict between the two. That is a far cry from preempting all claims against a manufacturer because its device had received regulatory approval, as the Seventh Circuit did here.

As we have noted (Pet. 13 n.2), the Seventh Circuit's view of MDA preemption is most similar to that expressed in *National Women's Health Network, Inc. v. A.H. Robins Co., Inc.*, 545 F.Supp. 1177, 1181 (D. Mass. 1982), but the preemption ruling there was expressly rejected by the FDA in a 1984 advisory opinion (18a-19a), which concluded that state tort remedies are *not* preempted by the MDA. Rather than challenge that advisory opinion on its merits, respondent notes only that the opinion did not pertain specifically to IOLs and that it might be revoked in the future (Opp. 18 n.3). In fact, the advisory opinion was issued by the FDA's Associate Commissioner for Regulatory Affairs pursuant to regulation, *see* 21 C.F.R. § 808.5, "represents the formal opinion of the FDA" which the Agency "is obligate[d] ... to follow," *id.* § 10.85(e), and is, if anything, a stronger barometer of FDA policy than the regulatory commentary deferred to by this

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[1] *See, e.g., Moore v. Kimberly Clark Corp.*, 867 F.2d 243 (5th Cir. 1989); *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. Unit B 1981); *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (N.J. 1978).

Court in *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714 (1985). Whatever the precise legal status of the advisory opinion, at the very least it illustrates the court of appeals' disregard for the FDA's narrow view of MDA preemption and, thus, highlights the need for review here.

3. Respondent is also mistaken in its assertion that the preemption ruling here is of "limited" impact (Opp. 8). First, the Seventh Circuit's decision, on its own terms, preempts state-law claims against manufacturers of *all* investigational devices, since the approval procedures for other investigational devices are virtually the same as those for IOLs. *See* 21 C.F.R. Part 812. This would involve millions of devices. Indeed, according to the informed consent form used here, the type of IOL implanted in petitioner alone was slated for use in 200,000 patients.[2]

Furthermore, most *non*-investigational devices are also subject to FDA pre-market approval. *See* 21 U.S.C. §§ 360e, 360(k); 21 C.F.R. Part 814 (pre-market approval procedures). Thus, under the court of appeals' analysis, claims against the manufacturers of *all* FDA-approved devices would also be preempted.

4. Finally, respondent has devoted an entire section of its opposition to showing that we have failed to preserve a claim concerning the adequacy of informed consent, which we have not made in this Court (Opp. 9-10). The issue of

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[2] The theme running through the court of appeals' opinion is that the implantation of petitioner's IOL was part of a small scientific "experiment" (5a-7a). However, IOLs, like other investigational devices, are commercially marketed, and indeed, were marketed for years on a non-investigational basis until health questions were raised. *See Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1283 (D.C. Cir. 1983).

whether petitioner assumed the risks of his operation, by virtue of signing a consent form, is a question of Illinois law (Pet. 22), and presents no issue for review. Nor does petitioner challenge here whether the consent form he signed conformed to federal law, although we do not believe that it did.

The only question presented is preemption, and the only reason that petitioner referred to the FDA's informed consent regulation is to show that the ruling below is also inconsistent with that regulation, which forbids a manufacturer of an investigational device to disclaim its liability for negligence or demand the release of a patient's legal rights. 21 C.F.R. § 50.20. Because the court of appeals held that all of petitioner's claims were preempted (7a), it effectively renders § 50.20 a nullity with respect to device manufacturers and undermines this Court's precedents, which are loathe to find preemption where the plaintiff would be left without a state *or* federal remedy (Pet. 21-23). On this score, contrary to respondent's conclusory assertion (Opp. 9), the decision of the court of appeals is squarely in conflict with the holding in *Mitchell v. IOLAB Corp.*, 700 F. Supp. 877 (E.D. La. 1988), as Judge Posner noted in the very first paragraph of his opinion (1a). This Court should grant review to resolve that conflict, as well as for the other reasons set out in the petition.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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